DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Changzhou Dingjian Medical Appliance Company, Ltd
% Mr. Mike Gu
OSMUNDA Medical Device Consulting Company, Ltd
7th Floor Jingui Business Buildng No. 982
Cogyuan Road, Baiyun District
Guangzhou, 510420 Guangdong
China

June 5, 2015

Re: K143002/S003
Trade/Device Name: Metallic Locking Bone Plate and Screw System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: May 25, 2015
Received: May 28, 2015

Dear Mr. Mike Gu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K143002

Device Name
Metallic Locking Bone Plate and Screw System

Indications for Use *(Describe)*

The Metallic Locking Bone Plate and Screws System are intended for adult patients with age above 21 as indicated for fixation of fractures, including ulna, radius, humerus, femur and tibia.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

D&J medical 鼎健骨科

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

I. SUBMITTER

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Date Prepared: April 13, 2015

II. DEVICE

Name of Device: Metallic Locking Bone Plate and Screw System

Common/Usual Name: Bone Fixation Plate and Bone Fixation Screw

Classification Names: Plate, Fixation, Bone (21 CFR 888.3030)

Screw, Fixation, Bone (21 CFR 888.3040)

Regulation Class: II

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510(k) Premarket Notification Submission_ Metallic Locking Bone Plate and Screw System

Product Code: HRS and HWC

III. PREDICATE DEVICE

Locking Bone Plates and Screws K130340;

Spacer K123918;

These predicates have not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The proposed device, Metallic Locking Bone Plate and Screw System consists of bone plate and screw. The bone plates are used for internal fixation of bone fracture, including ulna, radius, humerus, femur and tibia. Implant is made of Ti6Al4V Eli and titanium which conforms to ASTM F 136 and ASTM F67.

The proposed devices are provided un-sterilized. They shall be sterilized prior to use by healthcare provider. The proposed devices shall never be reused.

V. INDICATIONS FOR USE

The Metallic Locking Bone Plate and Screw System are intended for adult patients with age above 21 as indicated for fixation of fractures, including ulna, radius, humerus, femur and tibia.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Metallic Locking Bone Plate and Screw System employs the same technology as its predicate devices K130340 and K123918.

The Metallic Locking Bone Plate and Screw System is a structure formed by locking plate (which has at least one taper-thread hole) and locking screw (which has a head of taper-thread). Wherein the metal locking plate is a fracture fixation device with threaded holes, When the screw is revolved tightened in the plate, the plate system becomes an angle-fixed device. Locking plate can have both locking and non-locking screw holes fitting with various types of screws (also known as locking compression plate). In practice, positioning a plurality of screws in the locking plate maintains fracture anatomical reduction, which restores physiological function after bone healing.

Specification	**Predicate Device** **Locking Bone Plates and Screws K 130340**	**Proposed Device** **Metallic locking bone plate and screw system**
Manufacturer	Weigao Orthopaedic Device Co., Ltd.	Changzhou Dingjian Medical Appliance Co., Ltd.
Class	II	II
Product Code	Plate: HRS; Screw: HWC	Plate: HRS; Screw: HWC
Regulation Number	Plate: 21CFR 888.3030 Screw: 21CFR 888.3040	Plate: 21CFR 888.3030 Screw: 21CFR 888.3040
Intended Use	Locking bone plates and screws are intended for adult patients with age above 21 as indicated for fixation of fracture.	Metallic locking bone plate and screw systemis intended for adult patients with age above 21 as indicated for fixation of fracture.
Indications for Use	Bone fracture in ulna, radius, humerus, femur and tibia	Bone fracture in ulna, radius, humerus, femur and tibia
Patient Population	Adult patients of age above 21	Adult patients of age above 21
Prescription/OTC Use	Prescription use	Prescription use
Mechanical Performance	FOR PLATES: ASTM F 382-99 FOR SCREWS: ASTM F543-07	FOR PLATES: ASTM F 382-99(2008) FOR SCREWS: ASTM F543-07
Materials	PLATES: titanium which conforms to ASTM F67 Screw: Titanium alloy (TiAl4V ELI) which conforms to ASTM F136	PLATES: titanium which conforms to ASTM F67 Screw: Titanium alloy (TiAl4V ELI) which conforms to ASTM F136
Biocompatibility	PLATES: titanium which conforms to ASTM F67 Screw: Titanium alloy (TiAl4V ELI) which conforms to ASTM F136	PLATES: titanium which conforms to ASTM F67 Screw: Titanium alloy (TiAl4V ELI) which conforms to ASTM F136
Sterility	Provided as non-sterile, needs autoclave prior to use	Provided as non-sterile, needs steam sterilization prior to use

Test items for bone plates	Static four point bending Dynamic four point bending	Static four point bending Dynamic four point bending
Test items for bone screws	Torsional properties Driving torque Pull-out test	Torsional properties Driving torque Pull-out test

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

No clinical performance testing:

Bench tests were conducted to verify that proposed device meets all design specifications as was substantially equivalence to the predicate device. The following bench testing was performed to support a determination of substantial equivalence:

ASTM F382 standard specification and test method for metallic bone plates, including the following items:

- Static four point bending
- Dynamic four point bending

ASTM F543 standard specification and test methods for metallic medical bone screw including the following item:

- Torsional properties
- Driving torque
- Pullout test

Animal and clinical study

The subject of this premarket submission, metallic locking bone plate system, does not require clinical studies to support substantial equivalence.

VIII. CONCLUSIONS

The non-clinical data support the safety of the device and the performance testing report demonstrate that the metallic locking bone plate system should perform as intended in the specified use conditions. Changzhou Dingjian Medical Appliance Co., Ltd., Inc considers the metallic locking bone plate system does not raise any new issues of safety or effectiveness.